



# Recommendations and Reports

# Adult Immunization Programs in Nontraditional Settings: Quality Standards and Guidance for Program Evaluation

A Report of the National Vaccine Advisory Committee

## and

# Use of Standing Orders Programs to Increase Adult Vaccination Rates

Recommendations of the Advisory Committee on Immunization Practices

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
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## **Contents**

Adult Immunization Programs in Nontraditional Settings: Quality Standa	ards
and Guidance for Program Evaluation	1
Background	1
Introduction	
Purpose of the National Vaccine Advisory Committee Workshop	) 2
Workshop Participants	3
Summary of Workshop Presentations	3
Examples of Adult Immunization Programs	
in Nontraditional Settings	3
New Settings and Incentives for Immunization Programs	4
Benefits of Adult Immunization Programs in Nontraditional Setting	s 5
Access and Convenience	
Reduced Cost for Vaccinations	5
Increased Awareness for Vaccinations Among Adults	5
Challenges of Adult Immunization Programs	
in Nontraditional Settings	5
Adverse Reactions to Vaccines	5
Recordkeeping	6
Liability of Health-Care Providers	6
Legal Regulations	
Integrating Vaccine Programs in Nontraditional	
and Traditional Settings	6
Quality of Services	7
Future Considerations and Priorities	7
Guidance From NVAC for Conducting Adult Immunization Program	S
in Nontraditional Settings	8
Standard 1: Information and Education for Vaccinees	8
Standard 2: Vaccine Storage and Handling	8
Standard 3: Immunization History	9
Standard 4: Contraindications	9
Standard 5: Recordkeeping	
Standard 6: Vaccine Administration	11
Standard 7: Adverse Events	11
Conclusion	11
References	12
Use of Standing Orders Programs to Increase Adult Vaccination Rates	15
Introduction	
Background	
Implementation Guidelines	
Conclusion	
References	

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# Adult Immunization Programs in Nontraditional Settings: Quality Standards and Guidance for Program Evaluation

## A Report of the National Vaccine Advisory Committee

## Summary

This report provides a summary of the National Vaccine Advisory Committee's (NVAC) workshop on adult immunization programs in nontraditional settings, quality standards for such programs, and guidance for program evaluation. Throughout the United States, an increasing number of adults are receiving vaccine in nontraditional settings (e.g., pharmacies and churches). Immunization programs in nontraditional settings are often more accessible and convenient than a health-care provider's office or a public health clinic, especially for medically underserved adults (e.g., economically disadvantaged, inner city, and minority populations). Medically underserved adults might be at particular risk for undervaccination because they are often without a medical home (i.e., a regular point of contact where their health-care needs are met). Immunization programs in nontraditional settings might enhance the capacity of the health-care system to effectively deliver vaccine to adults by increasing the number and types of sites where adults can receive vaccine. NVAC has recognized that strategies need to be developed to make vaccines available to all adults and that the number of immunization programs in nontraditional settings is increasing. Therefore, the Committee issues the following report, including quality standards and guidance for program evaluation.

## **BACKGROUND**

Approximately 45,000 adults in the United States die annually of complications from influenza, pneumococcal infections, and hepatitis B — the primary vaccine-preventable diseases affecting adults. The total economic cost of treating these vaccine-preventable diseases among adults, excluding the value of years of life lost, exceeds \$10 billion each year. Although effective vaccines to prevent these diseases are available, they are widely underutilized (1,2). This underutilization reflects a lack of emphasis on vaccines for adults in comparison with the more substantial emphasis on vaccines for children.

Influenza and pneumococcal vaccine coverage rates for adults aged  $\geq$ 65 years vary by race and ethnicity (2). In 1997, influenza vaccine coverage rates ranged from 67.2% among non-Hispanic whites to 50.2% among non-Hispanic blacks (2). Pneumococcal vaccine coverage rates were even lower: 47.3% of white adults aged  $\geq$ 65 years reported receiving pneumococcal vaccine compared with 34.1% of Hispanics and 29.7% of blacks (2). Disease burden also varies by race and ethnicity. Blacks have a threefold to fivefold increased risk for developing life-threatening invasive pneumococcal disease compared with whites (3–5).

A recommendation by a health-care provider is a key factor determining whether an adult patient will be vaccinated (6). Medically underserved adults (e.g., economically disadvantaged, inner city, and minority populations) might be at particular risk for underimmunization because they are often without a medical home (i.e., a regular point of contact where their health-care needs are met) and might not have regular access to a health-care provider (7–10). Therefore, to reach medically underserved adults, strategies to increase vaccine-seeking behavior are critically needed. One such strategy involves offering vaccine to adults in nontraditional settings (e.g., pharmacies and churches) that might be more accessible and convenient than the office of a health-care provider or a public health clinic. Immunization programs in nontraditional settings might enhance the capacity of the health-care system to effectively deliver vaccine to adults by increasing the number and types of settings in which adults can receive vaccine.

## INTRODUCTION

# Purpose of the National Vaccine Advisory Committee Workshop

The National Vaccine Program Office sponsored a public meeting of the National Vaccine Advisory Committee's (NVAC) Adult Immunization Working Group on December 1–2, 1997, to explore adult immunization programs in nontraditional settings. The purpose of the workshop was

- to gain a better understanding of programs currently offering vaccines to adults in nontraditional settings,
- to identify potential benefits and challenges associated with administering vaccines in nontraditional settings,
- to identify additional nontraditional settings that could be explored and potentially used,
- to define areas where additional research is needed,
- to develop an effective immunization strategy integrating immunization programs in nontraditional settings with those in traditional settings, and
- to develop quality standards for immunization programs in nontraditional settings.

The workshop was limited to discussion regarding vaccines for adults because national vaccine coverage estimates for adults are substantially lower than the national goals established for this population, whereas coverage estimates for children approach or exceed national goals (2,7,11).

The purpose of this report is to provide a summary of discussions at the NVAC workshop so that persons who conduct or plan to conduct immunization programs in a nontraditional setting will have guidance regarding how to safely operate such a program. This report also highlights the importance of evaluating these programs by collecting data regarding associated benefits (e.g., increases in the number of adults vaccinated) and challenges (e.g., preventing fragmentation of care by reporting administration of vaccine to the primary-care provider of the vaccinee).

Influenza and pneumococcal vaccines constitute the majority of vaccines administered in nontraditional settings; therefore, this report focuses on these vaccines. If the types of vaccines administered in nontraditional settings increase, both the benefits and challenges could change.

## **Workshop Participants**

Workshop participants included members of the NVAC Adult Immunization Working Group and representatives from approximately 50 organizations, including federal and state governments, community and professional organizations, and private companies. Participants were identified through discussions with staff at CDC, the Health Resources and Services Administration, the National Coalition for Adult Immunization (NCAI), and other organizations. NCAI is composed of nearly 100 professional medical and health-care associations, advocacy groups, voluntary organizations, vaccine manufacturers, and government agencies. Workshop presenters were selected to ensure that a spectrum of viewpoints was represented.

## SUMMARY OF WORKSHOP PRESENTATIONS

Information regarding the U.S. Department of Health and Human Services' Adult Immunization Action Plan (1), vaccine coverage rates, and incidence of morbidity and mortality attributable to vaccine-preventable diseases among adults was presented. The American College of Physicians (ACP) and the National Medical Association provided physicians' perspectives of administration of vaccine in nontraditional settings. The benefits and challenges highlighted by these physicians were similar to those of other workshop participants. Benefits included increased access and convenience, reduced cost for vaccination, and increased awareness of the importance of vaccination. Challenges included ensuring that trained staff are available to treat potential adverse reactions to vaccines, keeping effective records, protecting health-care providers from liability, preventing fragmentation of care, and removing restrictive legal regulations.

NCAI and the National Council on Aging emphasized the importance of collaboration between public and private sectors and community-based organizations. A panel of representatives from community-based organizations providing services to traditionally underserved populations presented ways in which their clients might be more adequately cared for by the health-care profession (e.g., providing culturally and linguistically appropriate materials and outreach programs). Organizations that currently provide vaccines to adults in several nontraditional settings (including pharmacies, nontraditional clinical settings, retail establishments, dental care facilities, churches, the workplace, and the home) provided examples of the benefits and challenges experienced in these programs.

# Examples of Adult Immunization Programs in Nontraditional Settings

The Health Care Financing Administration's (HCFA) Horizons pilot project, a collaborative project between professional review organizations and nine historically black colleges and universities in eight southern states, was presented as an example of how the Federal government works with communities to provide vaccine in nontraditional settings. The goal of the Horizons project is to produce effective community-based

interventions for increasing vaccine coverage rates among black populations. Tennessee's Horizons project has provided vaccines to adults in approximately 14 non-traditional settings, including shopping malls, senior citizen centers, nutrition sites, mobile units, grocery stores, voting sites, parks, and public housing projects.

Pharmacies in the United States are increasing their participation in vaccination activities (12). Pharmacists are functioning as a) vaccine advocates, by educating their clients about the importance of vaccines; b) vaccine facilitators, by hosting vaccine clinics at pharmacies; and c) vaccine administrators, by vaccinating their clients. The American Pharmaceutical Association and CDC's National Immunization Program have developed a training course to prepare pharmacists for active participation in immunization programs (13). Twenty-six states have statutes that permit pharmacists to administer vaccine. Accessability of pharmacists and the degree of trust between pharmacists and patients were suggested as factors that provide important opportunities for pharmacists to educate adults about the benefits of vaccines and, in some cases, administer vaccine.

Nurse practitioners, visiting nurses, and members of the National Black Nurses Association (NBNA) also are involved in immunization programs in nontraditional settings. Nurse practitioners, using mobile-community health centers, often provide care to traditionally underserved homeless and migrant workers and a large population of older adults who reside in rural or inner city areas. NBNA and the Visiting Nurses Association often staff immunization programs operating in nontraditional settings, including the workplace, pharmacies, and churches.

A representative from the American Association of Occupational Health Nurses noted that employers can be involved in workplace immunization activities on three levels: a) providing vaccines at the work site, administered by their own medical staff; b) contracting with health-care providers to administer vaccine at the work site; and/or c) including preventive care benefits (e.g., vaccinations) in health plans for employees. Employers generally are interested in increasing employee productivity; therefore, decreased employee absenteeism associated with receiving influenza vaccine should be highlighted (14). Potential barriers to workplace vaccination programs include employers being reluctant to disrupt work schedules or to offer vaccine to employees covered by health plans. Workplaces with a small number of employees might not be able to provide vaccination programs on their own but might be able to unite with other offices and provide vaccines in a centralized site within an office park.

## **New Settings and Incentives for Immunization Programs**

Several additional nontraditional settings in which vaccines might be provided include soup kitchens, prisons, sheltered workshops for persons with disabilities, casinos, bingo halls, adult day care centers, major transit points, and polling stations on election days. Designation of mass immunization days (analogous to national immunization days for polio vaccination in endemic areas [15]) during which vaccinations are provided in several different settings was suggested. New incentive or endorsement programs that might increase the demand for vaccinations were also presented. For example, retail coupons and endorsement by sports teams were suggested as potential ways to enhance vaccine-seeking behavior among adults.

# BENEFITS OF ADULT IMMUNIZATION PROGRAMS IN NONTRADITIONAL SETTINGS

## **Access and Convenience**

The most common benefits of administering vaccine in nontraditional settings noted by workshop presenters are increased access and convenience. Providing vaccines in settings readily accessible to adults who are most in need of the services is critical. For many adults, the need to use transportation to reach a health-care provider is a barrier to receiving preventive services (7,9). This barrier might be eliminated by offering preventive services (e.g., administration of vaccines) in a neighborhood retail establishment, church, or other convenient location. Eliminating the need for making an appointment in advance and avoiding the waiting time often associated with a clinic or office visit are factors that also might increase the vaccine-seeking behavior of some adults (8,9).

## **Reduced Cost for Vaccinations**

The reduced cost of receiving vaccines in nontraditional settings compared with traditional settings is another potential benefit. The current cost of administering influenza and pneumococcal vaccines in a nontraditional setting is \$10–\$15 and \$15–\$20, respectively. Adults without health insurance might be willing to pay for a vaccine administered in a nontraditional setting when they would be unwilling or unable to pay the greater cost associated with a physician's office visit (16,17). For adults who are covered by Medicare, HCFA has mandated reimbursement for health-care providers who administer influenza vaccine, regardless of the setting, even if the health-care provider is not a member of the vaccinee's health-care plan.

## **Increased Awareness for Vaccinations Among Adults**

An indirect benefit of administering vaccine in nontraditional settings is increased public awareness of the need for adult immunization. This benefit is realized in two ways. First, many immunization programs operating in nontraditional settings use direct marketing to inform the community about their services and why they are important. Although marketing strategies might be directed toward promoting a specific site, the actual benefit is likely a general increase in public awareness regarding the importance and availability of vaccines for adults. Secondly, immunization programs in nontraditional settings often elicit media attention, which might increase community awareness of the need for vaccination of adults.

# CHALLENGES OF ADULT IMMUNIZATION PROGRAMS IN NONTRADITIONAL SETTINGS

## Adverse Reactions to Vaccines

Vaccine providers should be trained to manage adverse reactions that might occur. Concerns regarding postvaccination observation included: "Should direct observation

of vaccine recipients be routine? If so, what is the duration of observation? If a severe adverse reaction occurs, are trained and skilled personnel on site to respond appropriately?"

## Recordkeeping

Important factors regarding recordkeeping include how to determine which adults are in need of vaccines and how to prevent inappropriate revaccination.\* Immunization registries might play a role in resolving this issue; however, most existing immunization registries do not include information regarding adults. Until immunization registries routinely include this information, the primary-care provider and/or health department should be notified when a vaccine is administered in a nontraditional setting so that patient immunization records can be updated. In addition, vaccinees should be provided with wallet-sized vaccine records. These efforts will help ensure that adults are offered appropriately timed vaccines and that their vaccination status is accessible to their health-care provider in traditional or nontraditional settings and to other health-care providers who might offer them vaccines in nontraditional settings.

## **Liability of Health-Care Providers**

Many workshop participants considered liability protection for health-care providers an important component of any adult immunization program. Health-care providers might be more likely to promote and administer vaccines if they could be assured of not being held liable for incidents of rare but serious adverse reactions to vaccines.

## **Legal Regulations**

Workshop participants described several restrictive legal regulations regarding the administration of vaccines. In many states, legislation restricts who can administer vaccines and under what circumstances. In some areas, new immunization programs that might reach populations at high risk for disease could be hampered by restrictive legal regulations.

# **Integrating Vaccine Programs in Nontraditional and Traditional Settings**

One challenge of offering vaccines in a setting that does not provide other preventive services is fragmentation of care. Workshop participants acknowledged the importance of having a medical home to ensure appropriate and comprehensive preventive care, early diagnosis, and optimal therapy. Immunization programs in nontraditional settings should facilitate identification of medical homes for medically underserved adults who need a health-care provider. To promote integration of preventive care

<sup>\*</sup>Influenza vaccine should not be routinely administered more than once during an influenza season (18). Revaccination with pneumococcal vaccine one time, at least 5 years after initial vaccination, is recommended for persons at highest risk for pneumococcal infection (e.g., persons who are immunocompromised or who are asplenic) and those most likely to have a rapid decline in antibody concentrations. In addition, for persons vaccinated before age 65 years, a second dose should be administered at age ≥65 years, provided that ≥5 years have elapsed since the first dose (19).

services when an adult with a regular primary-care provider is vaccinated in a nontraditional setting, the primary-care provider should be notified by the vaccine provider of the patient's vaccination status. Vaccination status is often a marker for other health-care needs. Therefore, adults seeking vaccines in nontraditional settings also might need other preventive health services (e.g., mammograms and lipid screenings). In addition, these programs need systematic procedures (e.g., providing lists of nearby physicians and offering to schedule appointments) to ensure that referrals to primary-care providers are offered when appropriate and that relevant health promotion and disease prevention literature are available on site.

## **Quality of Services**

The mission of an immunization program and the motivation of the health-care providers who operate the program might affect the quality of services provided. Important components of quality care when administering vaccines in nontraditional settings include a) ability to handle adverse reactions, b) notification of the primary-care provider or health department when vaccines are administered, c) physician referral services, and d) providing education regarding other key preventive health measures.

## **FUTURE CONSIDERATIONS AND PRIORITIES**

The conclusions reached by workshop participants were based primarily on expert opinion and anecdotal information. Both workshop participants and NVAC recognize the need for research targeted at providing data that addresses the effectiveness of immunization programs in nontraditional settings in reaching previously unvaccinated adults.

NVAC recommends that program evaluation be conducted to determine the impact of immunization programs in nontraditional settings on vaccine coverage rates and vaccine-preventive disease rates among adults. Specifically, the following concerns should be addressed:

- Determine characteristics of persons receiving vaccine in nontraditional settings, including demographic characteristics, previous vaccine-seeking behavior, and previous and anticipated future use of the traditional medical system. A survey of persons using nontraditional settings for vaccination could provide these data.
- Determine characteristics of programs successfully reaching hard-to-reach, previously unvaccinated adults. Demonstration projects, including various types of programs (e.g., those operated by service versus for-profit organizations) in different locations, including churches, work sites, and pharmacies, need to be assessed to determine which combination of features creates the most successful program.
- Catalogue the types of services provided. The catalogue could include the
  following features: reporting to primary-care physician, referral to physician,
  provision of educational materials regarding the importance of other preventive
  care measures, the number of programs offering each service, and the effect of
  these services on program operating costs.

- Determine if the nontraditional settings in which vaccines are administered are accessible locations and settings in which medically underserved populations feel comfortable receiving vaccine. This information could be obtained by surveying these adults.
- Determine the potential effect of liability protection on physician practice patterns by surveying physicians.
- Determine reasons nonphysician providers in some states are not allowed to administer vaccines in nontraditional settings. These reasons could be addressed by surveying state legislators and health officials.

# GUIDANCE FROM NVAC FOR CONDUCTING ADULT IMMUNIZATION PROGRAMS IN NONTRADITIONAL SETTINGS

Although no formalized, coordinated effort to provide vaccinations in nontraditional settings exists at the national level, many adults are already receiving vaccine in these settings. To ensure the safety of persons receiving vaccines in these settings, NVAC has established seven quality standards for vaccine providers conducting or planning to conduct adult immunization programs in nontraditional settings.

Quality standards for immunization programs in nontraditional settings generally coincide with the quality standards for programs in traditional settings. NVAC's quality standards for immunization programs in nontraditional settings are consistent with existing adult immunization standards of the Advisory Committee on Immunization Practices (ACIP) (20), ACP (21), the Infectious Disease Society of America (22), and NCAI (23), with additional caveats specific to nontraditional settings.

## Standard 1: Information and Education for Vaccinees

Before receiving vaccine, the vaccinee must be given information about the risks and benefits associated with vaccination, including the CDC-developed Vaccination Information Statements that address the risks and benefits for 12 commonly administered vaccines, including influenza and pneumococcal vaccines. This information should be culturally and linguistically appropriate and written at a reading level that can be easily understood. The vaccine provider should be available to accurately address questions and concerns posed by the vaccinee.

Vaccinees should also be informed regarding the importance of having a medical home and receiving other preventive medical services. In addition, health promotion and disease prevention literature should be available on site and offered to the vaccinee.

## Standard 2: Vaccine Storage and Handling

Adherence to vaccine handling and storage recommendations included in vaccine package inserts is critical because mishandling and inappropriate storage can render vaccines ineffective. Influenza and pneumococcal vaccines are the primary vaccines administered in nontraditional settings. These vaccines should be stored at temperatures between 2 C and 8 C (38 F and 48 F), and records of storage temperature should

be maintained. Temperatures below freezing destroy the potency of these vaccines (24). Vaccine providers are responsible for ensuring appropriate storage of vaccines and should be trained accordingly. Storage procedures will become more complex if the types of vaccine offered in nontraditional settings increase.

## **Standard 3: Immunization History**

Prevaccination screening interviews should be conducted and immunization histories of vaccinees obtained before administering vaccines. At a minimum, the following information should be obtained from the vaccinee: vaccines previously received, preexisting health conditions, allergies, and adverse events that occurred after previous vaccinations. Consulting the vaccinee's medical record is the most reliable method of determining immunization status; however, this is not always feasible, especially among adults receiving vaccines in nontraditional settings. In many cases, the medical record might not be available or, if available, might not contain the most recent information, particularly if a vaccine was not administered by the vaccinee's primary-care provider. Although repeated pneumococcal vaccination (especially within 24 months) might be associated with local adverse reactions more severe than those occurring after initial vaccination (19,25), ACIP and ACP recommend that the vaccine be offered when vaccination status cannot be determined (19,21).

## **Standard 4: Contraindications**

Before administering vaccine, vaccine providers must assess the presence of contraindications. This assessment, part of the process of assessing the vaccinee's immunization history (Standard 3), should be made during the prevaccination screening interview. If a contraindication to immunization exists, this information should be provided to the primary-care provider or local health department and the vaccinee.

Severe systemic hypersensitivity reactions (including anaphylaxis) to egg protein, gelatin, neomycin, or streptomycin are contraindications for vaccines that contain these products (e.g., influenza vaccines). Live virus vaccines are generally contraindicated for adults who are immunocompromised and for women who are pregnant. These important contraindications affect only a small number of adults. Adults who need vaccine are more likely to not be offered it because of misconceptions concerning contraindications (see Box).

## Standard 5: Recordkeeping

Each time an adult receives a dose of vaccine, the following information should be recorded: vaccinee's name, age, preexisting health conditions, type of vaccine, dose, site and route of administration, name of the vaccine provider, date vaccine was administered, manufacturer and lot number, and date that the next dose is due. If possible, this information should be recorded in the vaccinee's medical file, sent to their primary-care provider, and given to the vaccinee. Retrievable files also should be maintained by the vaccine provider in compliance with general medical practice and state requirements.

Many adults do not have a primary-care provider and, even if they do, vaccine is often not administered by their primary-care provider. Geographic and occupational

mobility, changes in sources of health care, and economic factors often cause adults to see several health-care providers throughout their lifetime. As a result, vaccination records are often dispersed among a number of health-care providers. When vaccine is administered by a health-care provider other than the vaccinee's primary-care provider (e.g., vaccine received in a nontraditional setting), a vaccine card with the information noted in this standard should be provided to the primary-care provider or local health department (if no such provider can be identified) and the vaccinee. When possible, reminder notices should be sent to adults alerting them of when they are due for another vaccination.

#### **BOX. Contraindications to Immunization\***

## True Contraindications (Do Not Administer Vaccine)

- Anaphylactic reaction to a vaccine.
- Anaphylactic reaction to a vaccine component.
- Moderate or severe illness with or without fever.
- · Pregnancy.
- · Compromised immune system.

## False Contraindications (Vaccine May be Administered)

- Mild to moderate local reaction following a dosage of an injectable antigen.
- Low-grade or moderate fever following a previous vaccine dosage.
- Mild acute illness with or without fever.
- · Current antimicrobial therapy.
- Convalescent phase of illness.
- · Prematurity.
- Recent exposure to an infectious disease.
- History of penicillin or other nonspecific allergies or fact that relatives have such allergies.
- Pregnancy of mother or household contact.
- Unvaccinated household contact.
- · Breast-feeding.

<sup>\*</sup>This table is a modified version of the National Vaccine Advisory Committee's Standards for Pediatric Immunization Practices (CDC. Standards for pediatric immunization practices: recommendations of the National Vaccine Advisory Committee. MMWR 1993;42[No. RR-5]). Please consult with CDC's National Immunization Program for updates.

## Standard 6: Vaccine Administration

Health-care providers who administer vaccine must have the legal authority to do so and must be appropriately trained and licensed in all aspects of vaccine administration, including a) proper storage and handling of vaccines, b) information to be elicited from clients before vaccination (Standard 3), c) information to be given to clients before vaccination (Vaccine Information Statements), d) techniques for vaccine administration (20), and e) ability to handle adverse reactions.

Specific information regarding the recommended route of administration and appropriate dose is included in the package insert of each vaccine. Most vaccines are administered intramuscularly or subcutaneously. The dose indicated in the insert should be the dose administered. Administering one half of the recommended dose to potentially reduce the risk for adverse reaction has not been demonstrated to be an effective method of reducing adverse reactions and could result in inadequate protection against disease (26).

## Standard 7: Adverse Events

Vaccine providers must be trained to recognize and treat adverse reactions, and the equipment needed to do so must be available on site. Vaccines are safe and effective; however, adverse events, ranging from minor, local reactions to severe systemic illness, occasionally occur following vaccination. Although severe, systemic reactions are rare, they can be life-threatening. Vaccine providers should be trained to use medications (epinephrine, atropine, and sodium bicarbonate) and conduct procedures necessary to maintain the airway and manage cardiovascular collapse (basic and advanced cardiopulmonary resuscitation [CPR], operation of a defibrillator, and use of a self-reinflating ventilating bag [Ambu bag] to provide positive pressure ventilation during resuscitation). Vaccine providers must be in close proximity to a telephone so that emergency medical personnel can be summoned immediately, if necessary.

Vaccinees should be monitored for adverse reactions after receiving vaccine. If a severe adverse reaction occurs while the vaccinee is on site or any time after receiving vaccine, the primary-care provider or local health department should be notified.

To improve knowledge about vaccines and vaccine-associated adverse reactions, all serious adverse events should be reported to the Vaccine Adverse Event Reporting System (VAERS) (21). VAERS reporting forms and assistance can be obtained by telephone (1-800-822-7967) or through the CDC Internet site at <a href="http://www.cdc.gov/nip/vaers.htm">http://www.cdc.gov/nip/vaers.htm</a>.

## CONCLUSION

The ability of vaccines to save lives and prevent suffering extends beyond child-hood. As with childhood vaccines, adult vaccines are a cost-effective means of preventing disease (27,28). To realize these benefits, vaccines must be made readily available to the public. Although rates of vaccine coverage among adults are increasing, many adults (especially among economically disadvantaged, inner city, and minority populations) are not receiving appropriate vaccinations (2). Enhancing educational efforts and increasing the number and types of programs (e.g., standing orders [29] and non-traditional settings) safely administering vaccine to adults might increase the number of adults receiving vaccines and the associated benefits.

Educating health-care providers and the public is the cornerstone of an effective vaccination strategy. The Adult Immunization Action Plan (1) emphasizes the need for physicians and other health-care providers to recognize both the severity of influenza and pneumococcal disease and the safety and effectiveness of vaccines so they consistently offer vaccines to their patients. Physicians' recommendations influence patients' decisions to receive vaccine, regardless of the patients' initial attitude (6). However, some adults who need vaccination receive medical care but are not offered vaccine, whereas others might not have regular contact with traditional health-care settings. For these reasons, increased efforts to educate the public as well as health-care providers are needed. The 1994 NVAC report on adult immunization concluded that "better public understanding of the seriousness of vaccine-preventable diseases and the benefits of vaccination will be essential if there are to be improvements in adult immunization" (30).

An essential step toward creating an effective immunization infrastructure integrating traditional and nontraditional immunization programs is to determine the role each type of program has in the overall immunization strategy. Data from immunization programs in traditional and nontraditional settings are needed to assess who receives vaccine in which settings and why they choose that setting. Data characterizing persons who do not receive vaccine and their reasons for not getting vaccinated also are needed. These data will facilitate the development of a comprehensive immunization strategy to increase immunization coverage in all segments of the adult population.

Integration of nontraditional immunization programs with the existing health-care infrastructure provides the potential to increase vaccine coverage rates and decrease vaccine-preventable diseases among adults. To do so most effectively, the specific contributions of immunization programs in traditional and nontraditional settings need to be established, and the quality standards in this report need to be implemented. The efforts that effectively lowered vaccine-preventable disease rates among children now need to be targeted toward developing new and effective immunization programs that will make appropriate vaccines readily accessible to adults.

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## **Use of Standing Orders Programs to Increase Adult Vaccination Rates**

Recommendations of the Advisory Committee on Immunization Practices

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# Use of Standing Orders Programs to Increase Adult Vaccination Rates

## Recommendations of the Advisory Committee on Immunization Practices

### Summary

The Advisory Committee on Immunization Practices recognizes the need for evidence-based policy to improve the delivery and receipt of immunization services recommended for adults (i.e., persons aged ≥18 years). Two recent, systematic reviews of the health services research literature recommended standing orders programs as an effective organizational intervention to improve vaccination coverage rates among adults. This report briefly reviews the evidence on the effectiveness of standing orders programs, describes standards for program implementation, and recommends initiating these programs to improve immunization coverage in several traditional and nontraditional settings.

## INTRODUCTION

Standing orders programs authorize nurses and pharmacists to administer vaccinations according to an institution- or physician-approved protocol without a physician's exam. These programs have documented improved vaccination rates among adults. Standing orders programs can be used in inpatient and outpatient facilities, long-termcare facilities, managed-care organizations, assisted living facilities, correctional facilities, pharmacies, adult workplaces, and home health-care agencies to vaccinate patient, client, resident, and employee populations. The Advisory Committee on Immunization Practices (ACIP) recommends standing orders for influenza and pneumococcal vaccinations (1,2). Recently, systematic literature reviews by the Task Force for Community Preventive Services (3) and the Southern California Evidence-Based Practice Center–RAND endorsed these programs for adult populations (4).

This report briefly reviews the evidence regarding the effectiveness of standing orders programs in improving adult vaccination coverage rates and recommends prioritizing these programs for influenza and pneumococcal vaccinations, to have the greatest impact on the burden of vaccine-preventable diseases in the United States. Standing orders programs are also recommended for other vaccines, including hepatitis B vaccine and diphtheria and tetanus toxoid vaccines, when feasible.

## **BACKGROUND**

Epidemics of influenza occur during the winter months nearly every year and are responsible for an average of approximately 20,000 deaths per year in the United States (5,6). Influenza viruses cause disease in all age groups (7,8), but rates of serious morbidity and mortality are highest among persons aged  $\geq 65$  years and persons of any age who have medical conditions that place them at high risk for complications from influ-

enza (2,9-11). Pneumococcal disease accounts for approximately 3,000 cases of meningitis, 50,000 cases of bacteremia, and 500,000 cases of pneumonia each year (1) and is responsible for more deaths than any other vaccine-preventable bacterial disease (12). Despite antimicrobial therapy and intensive medical care, the overall case-fatality rate for pneumococcal bacteremia is 15%–20% among adults (i.e., persons aged  $\geq$ 18 years) (1). Among persons aged  $\geq$ 65 years, case-fatality rates can be as high as 40% (13).

In recent years, a rapid emergence of antimicrobial resistance among pneumococci, especially to penicillin, has occurred. Increasing pneumococcal vaccination rates could help prevent invasive pneumococcal disease caused by vaccine-type, multidrug-resistant pneumococci. Outbreaks of pneumococcal disease caused by a single drug-resistant pneumococcal serotype have occurred in institutional settings, including nursing homes (14,15). In 1999, because of concerns about pneumococcal antimicrobial resistance and underuse of pneumococcal vaccine, the American Medical Association and several partner organizations issued a Quality Care Alert that supports ACIP's recommendations for pneumococcal vaccination (16).

Health services research indicates that influenza and pneumococcal vaccines are underused in institutional settings, even after they became covered benefits of Medicare Part B (1981 for pneumoccocal vaccine and 1993 for influenza vaccine) (17,18). Despite the availability of suitable vaccines, persons hospitalized with conditions for which influenza and pneumococcal vaccines are indicated are not usually assessed for vaccination status or vaccinated. Among persons who reported at least one hospitalization during the preceding year to the 1997 National Health Interview Survey, 83% of persons aged 18-64 years with medical conditions that put them at high risk and 55% of all persons aged ≥65 years reported not receiving pneumococcal vaccinations (CDC, unpublished data, 1999). Sixty-nine percent of persons aged 18-64 years with medical conditions that put them at high risk and 32% of all persons aged ≥65 years reported not receiving influenza vaccination (CDC, unpublished data, 1999). In 12 western states, 80% of Medicare beneficiaries hospitalized for pneumonia during September-December 1994 did not receive influenza vaccines; 65% did not receive pneumococcal vaccines (17). The 1995 National Nursing Home Survey estimated influenza and pneumococcal vaccination rates among residents in long-term-care facilities to be approximately 63% and 22%, respectively (18). These rates are far below the Healthy People 2010 objective of 90% for both vaccines among all persons aged ≥65 years (objective 14-29) (19). Coverage estimates for 1997 were approximately 64% for influenza vaccines and 28% for pneumococcal vaccines (CDC, unpublished data, 1999). Many longterm-care facilities have inadequate policies and procedures to prevent vaccine-preventable diseases among their vulnerable populations (20).

Several studies suggest that standing orders programs are more effective than other institution-based strategies in improving vaccination services. In one New York hospital, instituting a standing orders program for pneumococcal vaccination among persons aged ≥65 years and other patients at high risk increased the pneumococcal vaccination rate from 0% to 78% (21). In another study, pharmacists increased pneumococcal vaccination rates from 4.2% to 94% in one nursing facility and from 1.9% to 83% in a second facility, whereas the rates at a control facility increased from 0.9% to 4.0% (22). In a study of six small community hospitals in northern Minnesota, standing orders programs achieved an influenza vaccination rate of 40.3% among patients, compared with 17% using physician reminders and 9.6% using educational programs (23).

A study conducted in an ambulatory care clinic compared the use of nurse standing orders combined with other interventions, including patient and health-care provider reminders, with the use of patient and provider reminders alone. Pneumococcal vaccination rates per total patient population were 22%–25% for the nurse standing orders programs, compared with 5% when patient and provider reminders were used alone (24).

Based on the scientific evidence of effectiveness in improving vaccination rates in institutions, the Task Force for Community Preventive Services and the Southern California Evidence-Based Practice Center–RAND recommend standing orders programs for the vaccination of adults in hospitals, clinics, and nursing homes (3,4). Standing orders policies are acceptable to most primary-care physicians (25) and have resulted in higher vaccination rates than other vaccination delivery methods (4,26).

## **IMPLEMENTATION GUIDELINES**

Successful standing orders programs begin by documenting a plan for the program's infrastructure, key service-delivery components, and quality assurance. To ensure success, a committee should be formed that includes the organization's medical director, nursing director, infection-control and quality-control personnel, and medical or nursing staff representatives. This committee should write protocols for the following procedures:

- Identifying persons eligible for vaccination based on their age, their vaccination status (e.g., persons previously unvaccinated or due for vaccination according to the recommended schedule), or the presence of a medical condition that puts them at high risk.
- Providing adequate information to patients or their guardians regarding the risks for and benefits of a vaccine and documenting the delivery of that information.
- Recording patient refusals or medical contraindications.
- Recording administration of a vaccine(s) and any postvaccination adverse events, according to institution- or physician-approved protocol.
- Providing documentation of vaccine administration to patients and their primary-care providers.

Standing orders protocols should also specify that vaccines be administered by health-care professionals trained to a) screen patients for contraindications to vaccination, b) administer vaccines, and c) monitor patients for adverse events, in accordance with state and local regulations. Vaccine information statements developed by and available from CDC can be useful for risk/benefit counseling before administering a vaccine. All health-care personnel administering vaccines or providing care to vaccinated persons should be trained to report adverse outcomes to the Vaccine Adverse Events Reporting System (VAERS). The appropriate VAERS forms and contact information should be readily available in all facilities delivering vaccines.

The standards for adult immunization practice established by the National Coalition for Adult Immunization recommend that standing orders programs include a standard personal and institutional immunization record to verify the immunization status of

patients and staff members and to reduce the risk for inappropriate revaccination (27). A patient's primary-care provider should be able to override institutional standing orders when medically appropriate. Ongoing communication between the primary-care provider, vaccinee, and institutional staff members is recommended to reduce the possibility of inappropriate vaccinations.

None of the studies of standing orders programs for influenza and pneumococcal vaccination reported unnecessary or inappropriate vaccinations (3,4,21–23,26). If repeated pneumococcal vaccinations did occur, studies have indicated that the risk for adverse events beyond self-limited local reactions was minimal for a second dose administered 2–5 years after the primary dose (1,28). The risk for self-limited local injection site reactions does not represent a contraindication to revaccination with pneumococcal vaccine in recommended groups.

The policies and protocols for standing orders programs should include a quality assurance process to maintain appropriate standards of care. The feasibility and cost-effectiveness of standing orders programs in several settings need ongoing evaluation, with particular attention to safety and tracking of vaccinations (29). For example, preprinted admissions orders could improve the effectiveness of program staff members to assess the vaccination status of patients and to provide information about the risks for and benefits of administering vaccinations routinely upon admission to facilities.

Facility staff members should consider other potential benefits (e.g., sustainability over time) when developing standing orders programs (30). These programs could be adapted to other preventive services (e.g., mammography) to improve delivery of those services, and they could be used to improve clinic efficiency by reducing pressures on physicians' time (3).

## CONCLUSION

ACIP recommends that standing orders programs be used in long-term–care facilities under the supervision of a medical director to ensure the administration of recommended vaccinations for adults. ACIP also encourages the introduction of standing orders programs for vaccination of adults in other settings (e.g., inpatient and outpatient facilities, managed-care organizations, assisted living facilities, correctional facilities, pharmacies, adult workplaces, and home health-care agencies). Implementation of standing orders programs alone or combined with other effective interventions can help improve vaccination coverage by institutional providers (3,4,31). Because of the societal burden of influenza and pneumococcal disease, implementation of standing orders programs to improve adult vaccination coverage for these diseases should be a national public health priority.

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